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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/724,730 11/28/00 GROSSMAN

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PATTI SELAN, PATENT ADMINISTRATOR
APPLIED BIOSYSTEMS
850 LINCOLN CENTRE DRIVE
FOSTER CITY CA 94404

EXAMINER

EINSMANN, J

ART UNIT

PAPER NUMBER

1655
DATE MAILED:

10/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/724,730

Applicant(s)

GROSSMAN, PAUL D.

Examiner

Juliet C Einsmann

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 31 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 526.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is written in response applicant's correspondence submitted 7/31/01, paper number 7. Applicant's arguments have been thoroughly reviewed; all previous rejections are hereby withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 1, 2, 3, 5, 8, 9, 10, 11, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Grossman *et al.* (US 5514543).

Grossman *et al.* (US 5514543) teach a binary composition comprising a target specific portion for sequence specific hybridization to a target nucleic acid, and a tag; and a mobility modifier comprising a tail and a tag complement for binding the tag (see, for example, Figure 1A). The polynucleotide marked (22) is the tag complement. The portion marked (27) is the tail, which is made of a polymer, for example polyethylene oxide or a polypeptide chain (Col. 3, lines 59-61). The portion marked (24) is the tag (in this case shown bound to the tag complement). The portion of (26) which is not hybridized to the tag complement is the target

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specific portion, and this portion would inherently comprise a 3'-hydroxyl group. Grossman *et al.* exemplify a tag and tag complement which comprise the sequence TCC (Fig. 4A). The compositions taught by Grossman *et al.* include probe elements attached to a polymer chain which imparts a distinctive electrophoretic mobility in a sieving matrix to the associated probe pair (Col. 3, lines 6-10). In one embodiment the compositions taught by Grossman *et al.* include tails made of polyethyleneoxide units (Col. 8, lines 33-34). Furthermore, Grossman *et al.* teach compositions which include hybridization enhancers, such as magnesium chloride (Col. 28, line 40, for example).

4. Claims 1-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Collins *et al.* (US 6232462).

Collins *et al.* teach a binary composition comprising a target specific portion for sequence specific hybridization to a target nucleic acid, and a tag; and a mobility modifier comprising a tail and a tag complement for binding the tag (see, for example, Figure 3, center section). The polynucleotide marked with an LP at the end is the tag complement. The portion marked (LP) is the tail, which is made of a polymer, the polypeptide enzyme alkaline phosphate (Col. 29, lines 57-63). Furthermore, Collins *et al.* exemplify a tag complement which comprises CAG (see SEQ ID NO: 32). The portion marked that the LP probe is bound to is the tag (in this case shown bound to the tag complement). The target specific portion of the probe is shown in this case bound to the portion of the complex marked CE, and this portion would inherently comprise a 3'-hydroxyl group. Collins *et al.* teaches that each of these are polynucleotides, and that the term polynucleotide is generic to, and thus encompasses, peptide nucleic acids (Col. 5, lines 39-50).

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Furthermore, Collins *et al.* teaches compositions which comprise hybridization enhancers such as acridine and psoralen (Col. 6, lines 1-8).

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 4-10, 13, and 15-18 of copending Application No. 09/232000 in view of Grossman *et al.* (US 5514543).

The claims of the co-pending application are drawn to broader compositions than the instantly claimed invention. The co-pending claims do not specifically teach compositions in which the label is a mobility modifier.

Grossman *et al.* (US 5514543) teach compositions useful for detecting multiple sequences in a single assay. The compositions taught by Grossman *et al.* include probe elements attached to a polymer chain which imparts a distinctive electrophoretic mobility in a sieving matrix to the associated probe pair (Col. 3, lines 6-10). In one embodiment the compositions taught by Grossman *et al.* include tails made of polyethyleneoxide units (Col. 8, lines 33-34).

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Grossman *et al.* teach that these compositions are useful in methods to provide multiple probe-target complexes where the probe-complexes are resolved in a mobility-dependent analysis technique (Col. 2, line 66-Col. 3, line 12). Grossman *et al.* further teach labels attached to probes (See for example, Col. 9, lines 60-65).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the methods claimed in the instant application with the mobility modifiers taught by Grossman *et al.* instead of attaching the tag complements to an addressable array. The ordinary practitioner would have been motivated to make such a substitution because Grossman *et al.* expressly teaches that the use of mobility modifiers “allows a plurality of target sequences to be assayed in a single-assay format, with rapid identification of sequences according to the mobilities of different polymer chains associated with the sequence-specific labeled probes. The polymer chains allow for separation of single and double stranded oligonucleotides, in a simple chromatography or electrophoresis method. In particular, the method allows for effective fractionation of a plurality of oligonucleotides, all of which have similar or identical sizes (Col. 22, lines 35-43).”

This is a provisional obviousness-type double patenting rejection.

Conclusion

7. No claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Juliet C. Einsmann
Examiner
Art Unit 1655

October 16, 2001



W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600